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EXAMINER

LUM, LEON YUN BON

ART UNIT

PAPER NUMBER

1641

NOTIFICATION DATE

DELIVERY MODE

11/27/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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DETAILED ACTION

Status of Claims

Claims 1-4, 6-8, 10-11 and 13-33 are pending, with claims 14 and 17-31 withdrawn. Pursuant to the request to rejoin claims 18-21 in the response dated February 17, 2009, these claims have been rejoined. Accordingly, claims 1-4, 6-8, 10-11, 13, 15-16, 18-21 and 32-33 are therefore examined on the merits.

Election/Restrictions

Applicants' election in the response filed September 14, 2009 is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 10-11, 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,079,155 to Cox *et al.* ("Cox") in view of Great Britain Patent No. 857,689 ("the '689 patent"), already of record.

i. Independent claims 1, 15 and 16 are obvious

Cox describes a method of creating a solid support, comprising the steps of attaching a ligand to the support and then coating the support with a nonionic fluoro-surfactant. See column 5, lines 35-44. The nonionic fluorosurfactant provides for nonspecific binding. See column 2, lines 25-27. The portion of the support that attaches to the ligand is an "interlayer." *Id.* The interlayer can be hydrophobic. See column 8, line 22. Moreover, Cox describes using the support for immunoassay purposes. See column 9, lines 30-32. Accordingly, Cox teaches the instant claim except for the specific fluorinated nonionic surfactant.

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The '689 patent describes a fluorocarbon polymer that repels water and is resistance to absorption. See page 1, left column, lines 12-17; page 2, left column (first formula).

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Cox's method by including the fluorocarbon polymer described in the '689 patent. The skilled artisan would have made the modification because Cox requires a nonionic fluorosurfactant polymer for repelling molecules and the '689 patent's fluorocarbon polymer is one such example. Moreover, Cox does not limit the type of nonionic fluorosurfactant polymer. Accordingly, the skilled artisan would have had a reasonable expectation of success in combining the teachings of Cox and the '689 patent.

ii. Dependent claims 2, 10-11 and 13 are obvious

Regarding claim 2, the solid support can be porous. See column 5, lines 1-3.

Regarding claims 10-11 and 13, the ligand can be an antibody. See column 5, line 12.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of the '689 patent as applied to claim 1 above, and further in view of U.S. Patent No. 5,071,610 to Hagen *et al.* ("Hagen"), already of record.

Cox and the '689 patent do not teach a PTFE fibril matrix.

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Hagen describes a PTFE fibril matrix as a suitable support for a variety of biological applications, including diagnostics. See column 1, lines 12-14; column 3, lines 15-17.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Cox and the '689 patent's method by using a PTFE fibril matrix. The skilled artisan would have made the modification because Cox indicates that any polymer can be used as the substrate. See column 4, lines 66-67.

Accordingly, because the PTFE fibril matrix can be used for the same applications taught by Cox, see *supra* rejection of claim 1, the skilled artisan would have found it obvious to make the modification. Moreover, the skilled artisan would have had a reasonable expectation of success for the same reason.

Claims 4, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of the '689 patent as applied to claims 1 or 15 above, and further in view of U.S. Patent No. 5,077,210 to Eigler *et al.* ("Eigler").

Cox and the '689 patent, described above, do not teach a secondary blocking agent.

Eigler describes a method of immobilizing active agents onto a surface, the method comprising adding at least one blocking agent to prevent nonspecific action. See column 3, lines 33-37.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Cox and the '689 patent's method to include more than one

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blocking agent. In doing so, it would have been obvious to add to the method by including a separate step of depositing a secondary blocking agent. The skilled artisan would have recognized that adding one extra blocking agent would decrease the chance of nonspecific binding over just one blocking agent. Accordingly, the modification would have been obvious. For the same reason, the skilled artisan would have had a reasonable expectation of success.

Further regarding claim 4, the secondary blocking agent can be a protein. *Id.*

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of the '689 patent as applied to claim 1 above, and further in view of U.S. Patent No. 5,268,307 to Breillatt *et al.* ("Breillatt").

Cox and the '689 patent, described above, do not teach removing at least 50% or 90% of the adhered target molecules.

Breillatt describes releasing bound target substances as a way of increasing the sensitivity of detection. See column 10, line 66 to column 11, line 7.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Cox and the '689 patent's method to include releasing the bound target substances. The skilled artisan would have made the modification because Breillatt indicates that doing so will increase the sensitivity of detection.

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Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of the '689 patent and U.S. Patent No. 4,240,751 to Linnecke *et al.* ("Linnecke").

Cox and the '689 patent are described above and teach the instant claims except for instructions.

Linnecke describes instructions as part of an immunoassay kit to perform the immunoassay. See column 16, lines 21-24.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Cox and the '689 patent to include instructions. The skilled artisan would have modification because instructions allow a use to conduct and evaluate the immunoassay appropriate. Moreover, including instructions in with a kit requires only routine skill in the art. Therefore, the skilled artisan would have had a reasonable expectation of success in combining Linnecke's instructions with the method of Cox and the '689 patent.

Allowable Subject Matter

Notwithstanding the rejection under section 112, paragraph 6 above, Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the independent claims have been considered but are moot in view of the new grounds of rejection.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-

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2872. The examiner can normally be reached on Monday to Friday (8:30 am to 5:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon Y. Lum/
Examiner, Art Unit 1641

/Unsu Jung/
Primary Examiner, Art Unit 1641